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Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Date Submitted: June 17, 2004

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Sheet

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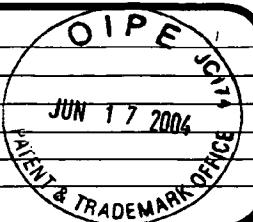
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Complete if Known

Application Number	10/734,644
Filing Date	12/15/2003
First Named Inventor	Jay BUA
Group Art Unit	1645
Examiner Name	Not yet assigned

Attorney Docket Number

029488-0112

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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FOREIGN PATENT DOCUMENTS

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/B.F./	A1	Charlotte ATKINSON et al., "Mammographic Patterns as a Predictive Biomarker of Breast Cancer Risk: Effect of Tamoxifen", Cancer Epidemiology, Biomarkers & Prevention, Vol. 8, October 1999, pp. 863-866.	
/B.F./	A2	J. BARRAT et al., "Effet <i>in vivo</i> de l'administration locale de progestérone sur l'activité mitotique des galactophores humains", J. Gynecol. Obstet. Biol. Reprod. 19: 269-274 1990.	
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/B.F./	A5	Norman F. BOYD et al., "Effects at Two Years of a Low-Fat High-Carbohydrate Diet on Radiologic Features of the Breast: Results from a Randomized Trial", Journal of the National Cancer Institute, Vol. 89, No. 7, April 2, 1997, pp. 488-496.	
/B.F./	A6	Jacques BRISSON et al., "Tamoxifen and Mammographic Breast Densities", Cancer Epidemiology, Biomarkers & Prevention, Vol. 9, September 2000, pp. 911-915.	
	A7	Bronaugh & Maibach, "Percutaneous Absorption Drugs-Cosmetics-Mechanisms-Methodology", Marcel Dekker Inc., New York, 1999.	

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/B.F./	A8	Celia BYRNE, "Studying Mammographic Density: Implications for Understanding Breast Cancer", Journal of the National Cancer Institute, Vol. 89, NO. 8, April 16, 1997, pp. 531-537.	
	A9	Philip CARTHEW et al., "Cumulative exposure to tamoxifen: DNA adducts and liver cancer in the rat", Arch Toxicol (2001) 75: 375-380.	
	A10	Gerard CHETRITE et al., "Effect of Promegestone, Tamoxifen, 4-Hydroxytamoxifen and ICI 164,384 on the Oestrone Sulphatase Activity of Human Breast Cancer Cells", Anticancer Research 13: 931-934 (1993).	
	A11	Eric C. DIETZE et al., "Tamoxifen but Not 4-Hydroxytamoxifen Initiates Apoptosis in p53(-) Normal Human Mammary Epithelial Cells by Inducing Mitochondrial Depolarization", The Journal of Biological Chemistry Vol. 276, No. 7, Issue of February 16, 2001, pp. 5384-5394.	
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	A13	Ian S. FENTIMAN, "Tamoxifen and Mastalgia an Emerging Indication", Drugs, Vol. 32, No. 6, December 1986, pp. 477-480.	
	A14	I.S. FENTIMAN et al., "Dosage and duration of tamoxifen treatment for mastalgia: a controlled trial", BR. J. SURG. September 1988, Vol. 75, No. 9, pp. 845-846.	
↓	A15	I.S. FENTIMAN et al., "Studies of tamoxifen in women with mastalgia*", The British Journal of Clinical Practice, Supplement 68, Vol. 43, No. 11, November 1989, pp. 34-36.	
/B.F./	A16	N. GIAMBIAGI et al., "IMMUNOLOGICAL DIFFERENCES BETWEEN THE ESTRADIOL-, TAMOXIFEN- AND 4-HYDROXY-TAMOXIFEN-ESTROGEN RECEPTOR COMPLEXES DETECTED BY TWO MONOClonAL ANTIBODIES", J. Steroid Biochem. Vol. 30, No. 1-6, pp. 213-217, 1988.	

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	A18	Jennifer A. HARVEY et al., "Short-term Cessation of Hormone Replacement Therapy and Improvement of Mammographic Specificity", Journal of the National Cancer Institute, Vol. 89, No. 21, November 5, 1997, pp. 1623-1625.	
	A19	IBIS Investigators, "First results from the International Breast Cancer Intervention Study (IBIS-I): a randomised prevention trial", The Lancet, Vol. 360, September 14, 2002, pp. 817-824.	
	A20	Susan JENKS, "Dense Breast Tissues May Hold Increased Cancer Risk for Some", Journal of the National Cancer Institute, Vol. 86, No. 8, April 20, 1994, pp. 578-580.	
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	A22	Karla KERLIKOWSKE MD et al., "Effect of Age, Breast Density, and Family History on the Sensitivity of First Screening Mammography", JAMA, vol. 276, No. 1, July 3, 1996, pp. 33-38.	
	A23	Z. KAUFMAN et al., "The Mammographic Parenchymal Patterns of Women on Hormonal Replacement Therapy", Clinical Radiology (1991), 43, 389-392.	
↓	A24	Thomas M. KOLB MD et al., "Comparison of the Performance of Screening Mammography, Physical Examination, and Breast US and Evaluation of Factors that Influence Them: An Analysis of 27,825 Patient Evaluations", Radiology, Vol. 225, No. 1, October 2002, pp. 165-175.	
/B.F./	A25	George G.J.M. KUIPER et al., "Comparison of the Ligand Binding Specificity and Transcript Tissue Distribution of Estrogen Receptors α and β ", Endocrinology, Vol. 138, No. 3, 1997, pp. 863-870.	

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/B.F./	A26	Frédérique KUTTENN et al., "MÉDECINE ET THÉRAPEUTIQUE", C.R. Acad. Sc. Paris, , Série III, No. 12, 1985, 300:457-461.	
	A27	Winnie LEUNG MD et al., "Mammographic density in women on postmenopausal hormone replacement therapy", SURGERY, Vol. 122, No. 4, October 1997, pp. 669-674.	
	A28	L. MA et al., "Case-Control Study of Factors Associated With Failure to Detect Breast Cancer by Mammography", Journal of the National Cancer Institute, Vol. 84, No. 10, May 20, 1992, pp. 781-784.	
	A29	Catherine MALET et al., "Tamoxifen and Hydroxytamoxifen Isomers versus Estradiol Effects on Normal Human Breast Cells in Culture", Cancer Research, Vol. 48, No. 24, December 15, 1988, pp. 7193-7199.	
	A30	Pierre MAUVAIS-JARVIS et al., "trans-4-Hydroxytamoxifen Concentration and Metabolism after Local Percutaneous Adminstration to Human Breast", Cancer Research, Vol. 46, March 1986, pp. 1521-1525.	
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	A32	Lawrence H. BLOCK PhD "Epidermal and Transdermal Drug Delivery", The Science and Practice of Pharmacy, Medicated Topicals, pp. 836-857 (2000).	
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/B.F./	A34	David W. ROBERTSON et al., "TAMOXIFEN ANTIESTROGENS, A COMPARISON OF THE ACTIVITY, PHARMACOKINETICS, AND METABOLIC ACTIVATION OF THE C/S AND TRANS ISOMERS OF TAMOXIFEN" Journal of Steroid Biochemistry, Vol. 16, pp. 1-13, (1982).	

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/B.F./	A35	Carolyn M. RUTTER, PhD et al., "Changes in Breast Density Associated With Initiation, Discontinuation, and Continuing Use of Hormone Replacement Therapy", JAMA, Vol. 285, No. 2, January 10, 2001, pp. 171-176.	
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